Dated: February 12, 2010.

Alexander Cristofaro,

Director, Office of Regulatory Policy and Management.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 790

[EPA–HQ–OPPT–2009–0894; FRL–8802–6]

RIN 2070–AJ59

Amendments to Enforceable Consent Agreement Procedural Rules

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to revise the procedures for developing Enforceable Consent Agreements (ECAs) to generate test data under the Toxic Substances Control Act (TSCA). The main features of the ECA process that EPA is proposing to change include when and how to initiate negotiations and inserting a firm deadline at which negotiations will terminate. EPA is also proposing to amend several sections in 40 CFR part 790 to place the ECA provisions in one section and the Interagency Testing Committee (ITC) provisions in a separate section, to make it clearer that there is one ECA negotiation procedure applicable to all circumstances when an ECA would be appropriate and to make conforming changes in other sections that reference the ECA procedures.

DATES: Comments must be received on or before March 22, 2010.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2009–0894, by one of the following methods:

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail*: Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Hand Delivery*: OPPT Document Control Office (DCO), EPA East Bldg., Rm. 6428, 1201 Constitution Ave., NW., Washington, DC. Attention: Docket ID Number EPA–HQ–OPPT–2009–0894. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 564–8930. Such deliveries are only accepted during the DCO's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to docket ID number EPA–HQ–OPPT–2009–0894. EPA's policy is that all comments received will be included in the docket without change and may be made available on-line at *http://www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov or e-mail. The regulations.gov website is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available electronically at *http://www.regulations.gov*, or, if only available in hard copy, at the OPPT Docket. The OPPT Docket is located in the EPA Docket Center (EPA/DC) at Rm. 3334, EPA West Bldg., 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566–1744, and the telephone number for the OPPT Docket is (202) 566–0280. Docket visitors are required to show photographic identification, pass through a metal detector, and sign the EPA visitor log. All visitor bags are processed through an X-ray machine and subject to search. Visitors will be provided an EPA/DC badge that must be visible at all times in the building and returned upon departure.

FOR FURTHER INFORMATION CONTACT: *For general information contact*: Colby Lintner, Regulatory Coordinator, Environmental Assistance Division (7408M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (202) 554–1404; e-mail address: *TSCA-Hotline@epa.gov*.

For technical information contact: Jessica Barkas, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (202) 250–8880; e-mail address: *barkas.jessica@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does This Action Apply to Me?

You may be potentially affected by this action if you manufacture (defined by statute to include import) or process chemical substances. Potentially affected entities may include, but are not limited to:

- Manufacturers (defined by statute to include importers) of chemical substances (NAICS codes 325 and 324110), e.g., chemical manufacturing and petroleum refineries.
- Processors of chemical substances (NAICS codes 325 and 324110), e.g., chemical manufacturing and petroleum refineries.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What Should I Consider As I Prepare My Comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that

you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

II. Background

A. What Action is the Agency Taking?

EPA promulgated the ECA rules at 40 CFR part 790 in 1986. The procedures were developed in consultation with the Natural Resources Defense Council and the Chemical Manufacturers Association; several public meetings to discuss the procedures were held before the procedural rule was promulgated as an interim final rule.

ECAs are enforceable agreements between EPA and one or more chemical manufacturers or processors to conduct specific testing on a particular chemical substance. These agreements are designed to provide EPA with data identified as necessary to evaluate a particular chemical substance without the need for EPA to first make the risk- or exposure-based findings for, or promulgate, a TSCA section 4 test rule, and without introducing delays inherent in the rulemaking process. ECAs were intended to permit EPA to obtain test data more quickly than test rules, while preserving opportunity for input from the public and the affected manufacturer(s).

When EPA promulgated the original ECA rules, it anticipated that the timeline for completing an ECA, from ITC recommendation to agreement finalization, would be 50 weeks. EPA indicated uncertainty about the feasibility of the schedule from the outset, noting in Appendix A to subpart E of part 790 that the schedule was subject to amendment, by rule, should it prove unrealistic in practice. Since the publication of the ECA rule, the average time to complete an ECA has been approximately two years and negotiations have taken well over two years for several chemicals. Negotiations for ECAs on many chemicals have been started but never formally concluded, or have been terminated. EPA now proposes to revise the ECA procedural rule to increase the efficiency and flexibility of the ECA process.

EPA recognizes the value of an open and transparent process for developing these agreements, and proposes to retain the opportunities for public involvement in negotiations, to review draft agreements, and to object to agreements. Key features that EPA is proposing to change involve determining when and how to initiate negotiations and inserting a firm deadline at which negotiations will terminate, and no ECA will be agreed to absent an affirmative decision by EPA to extend negotiations. EPA is also proposing to amend several sections in 40 CFR part 790 to place the ECA procedure in one section, to make it clearer that there is one ECA negotiation procedure applicable to all circumstances when an ECA would be appropriate, and to make conforming changes in other sections that reference the ECA procedures.

B. What is the Agency's Authority for Taking This Action?

Section 4 of TSCA authorizes EPA to require manufacturers and processors of chemical substances and mixtures to test these chemicals to generate data that is relevant to determining whether the chemicals present an unreasonable risk. Section 4(a) of TSCA empowers the Agency to promulgate rules which require such testing. Section 4 of TSCA provides implied authority to enter into enforceable consent agreements requiring testing where such agreements provide procedural safeguards equivalent to those that apply where testing is conducted by rule.

C. What is An ECA?

An ECA is an enforceable legal agreement between EPA and one or more private parties, such as a group of chemical manufacturers, specifying that those private parties will conduct testing on a given chemical substance to fill an EPA-identified need. The violation of the terms of an ECA is a prohibited act under TSCA and is enforceable under sections 16 and 17 of TSCA. In addition, chemicals subject to ECAs, similar to chemicals subject to test rules, are subject to certain additional provisions of TSCA (e.g., export notification under section 12 of TSCA). Because private parties enter ECAs voluntarily, EPA need not make findings as to unreasonable risk of injury to health or the environment, significant or substantial human exposure, or other findings that would be required to issue a final test rule. ECAs were conceived as a tool for EPA to acquire test data more expeditiously than could be achieved through the typical rulemaking process.

D. When Has EPA Used ECAs and Why is EPA Proposing to Modify the ECA Procedures?

Since 1986, EPA has published a number of **Federal Register** documents announcing its interest in using ECAs to obtain various test data. In some instances, EPA selected one or more chemical substances for testing consideration based on an ITC recommendation or designation (see, e.g., ECA for cyclohexane, 59 FR 59660 (November 18, 1994) (FRL–4909–5)). In other instances, EPA selected the substance or substances based on its own initiative (see, e.g., ECA for 1,2-ethylene dichloride, 68 FR 33125 (June 3, 2003) (FRL–7300–6)). ECAs have been used for testing single chemical substances and for testing multiple chemical substances, usually chemical substances related to one another. For the reasons summarized in Unit II.A. and further explained Unit II.D., E., and F., EPA has been using ECAs with declining frequency over the last several years. EPA's data needs have not diminished, however, and the reduced number of ECAs has not been offset by an increase in the issuance of test rules. Because EPA would like to continue to use ECAs, where appropriate, it is proposing to amend the rules to make them quicker and easier to implement, to preserve existing provisions for transparency and adequate opportunities for public participation, and to make them easier for the public

to understand. EPA believes that these changes will increase Agency efficiency by enhancing EPA's ability to use ECAs where appropriate, thereby permitting EPA to focus regulatory activity (and resources) on those chemicals for which ECAs are inappropriate or for which agreement cannot be reached significantly faster than a rule can be promulgated.

E. When Does EPA Use Test Rules?

EPA typically uses test rules when it makes certain findings specified under section 4(a) of TSCA. They include the finding that either the manufacture, distribution in commerce, processing, use, or disposal of a chemical substance or mixture, or that any combination of such activities, may present an unreasonable risk of injury to health or the environment; or that a chemical substance is or will be produced in substantial quantities and it either enters or may reasonably be anticipated to enter the environment in substantial quantities, or there is or may be significant or substantial human exposure to that chemical substance or mixture. In addition, they include the findings that "there are insufficient data or experience upon which the effects of the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or any combination of such activities on health or the environment can reasonably be determined or predicted," and that "testing of such substance or mixture with respect to such effects is necessary to develop such data" (15 U.S.C. 2603).

EPA has typically used test rules in circumstances where the ITC has designated a chemical for testing. In such circumstances, EPA has a statutory duty to either initiate a proceeding for a test rule within 12 months of the designation, or publish reasons why a test rule is not necessary. EPA has also recently used test rules to require testing of several high production volume (HPV) chemicals.

More generally, EPA may pursue a test rule whenever EPA believes it can make the necessary findings. This includes situations where no party has volunteered to participate in ECA negotiations, where ECA negotiations are tried and fail, where the testing protocols or other considerations are too complex or new to make negotiations an efficient means of requiring testing, or in other circumstances that lead EPA to believe that negotiations would be unlikely to produce an ECA.

F. What are the Specific Proposed Changes to the ECA Rule?

1. *Proposed reorganization of 40 CFR part 790, subpart B and removal of Appendix A to subpart E of part 790.* EPA is proposing to amend 40 CFR 790.20 and 40 CFR 790.22 by combining § 790.22 with portions of § 790.24, by consolidating § 790.20 with portions of § 790.26 and § 790.28, and by consolidating § 790.22 with § 790.28 to improve the organization of the rules, and to make it more clear that there is one ECA negotiation procedure for all situations in which ECAs are appropriate (generally, based on EPA's own initiative or an ITC recommendation).

EPA is proposing to move part of § 790.22 to § 790.20 so that all provisions pertaining to how ITC intends to carry out making recommendations or designations, and how EPA intends to respond to those ITC actions, are in one section, and so that all provisions pertaining to ECA development procedures (which can apply whether or not the ITC has made a recommendation or designation) are in another section. EPA proposes to expand the section currently numbered § 790.20(b)(2), which presently only covers recommendation without intent to designate, to include the same list of possible actions when ITC makes a recommendation, whether with or without intent to designate, and to move the procedures described in § 790.22(a) to § 790.20. The text presently at § 790.22(a) will replace § 790.20(b), and the current § 790.20(b) will be redesignated § 790.20(c). This will help centralize all of the ITC-related procedures and remove the potentially confusing ITC discussion from the ECA procedural rules. To further centralize and consolidate the ECA procedures, EPA proposes to move the criteria for determining when consensus is reached, currently in § 790.24 to § 790.22.

EPA proposes to remove § 790.26 (initiation and completion of rulemaking proceedings on ITC-designated chemicals) and § 790.28 (procedures for developing consent agreements and/or test rules for chemicals that have not been designated or recommended with intent to designate by the ITC). The procedures and explanations in these sections are either needlessly duplicative or would be superseded by or incorporated into the proposed changes to § 790.20 (procedures that follow ITC recommendation and designation) and § 790.22 (ECA procedures). First, the proposed amended ECA procedures already articulate the principle (in proposed § 790.22(b)(4)) that EPA may proceed to rulemaking under TSCA section 4 if ECA negotiations are not successful. Second, for the reasons described in Unit II.F.1., EPA is proposing to remove the Appendix A and schedule table referred to in § 790.26(b), and the remainder of § 790.26(b) as duplicative of EPA's existing rulemaking obligations under the Administrative Procedures Act. Third, EPA is proposing to incorporate § 790.26(c) into the text of § 790.20(c)(1)(i) (§ 790.20(b)(1)(i) in the existing rules). Fourth, § 790.28, which describes the procedures for developing ECAs for chemicals that have not been designated or recommended with intent to designate by the ITC, is unnecessary in light of the proposed expansion of the scope of § 790.22. The procedures that EPA is proposing in § 790.22 will apply to all circumstances in which ECAs are appropriate, including chemicals that have not been designated or recommended with intent to designate by the ITC.

EPA proposes to remove Appendix A to subpart E of part 790, including the schedule table, because the Agency believes that the proposed revised procedures in § 790.20 and § 790.22 adequately explain timelines for meetings and notices and because EPA is proposing to limit the required number of meetings and notices associated with ECA negotiations. The table is merely illustrative and provides little additional explanatory utility. Furthermore, the schedule table commingles events relating to ITC recommendations-with-intent-to-designate and more generic events relating to all ECA negotiations in a manner that could generate confusion over what procedures apply when EPA wishes to acquire testing information on a chemical for which the ITC has not made a recommendation with intent to designate.

In addition to the changes discussed in Unit II.F.1., EPA proposes to make additional conforming and clarifying changes to § 790.20. The title of the section will be amended to include "recommendation with intent to designate," and the title of § 790.20(c) (currently § 790.20(b)) will be amended to include ITC "designations." Finally, EPA proposes to make a few conforming changes to § 790.1, including removing the reference to the Appendix A schedule table in § 790.1(d) and removing the statement in § 790.1(c), regarding EPA's intent to proceed with rulemaking if ECA negotiations are unsuccessful, because the proposed amended § 790.22(b)(4) includes a similar statement of intent.

2. *Proposed changes to the ECA procedures.* EPA is proposing to revise the ECA procedures to reflect that negotiation of an ECA for a chemical will not commence until EPA has received and evaluated a testing agreement proposal, and until EPA believes it is likely that proceeding with negotiation of a consent agreement, based on the proposal, would be an efficient and successful means of developing the test data. When evaluating testing proposals, EPA would generally consider factors such as whether it appears to address EPA's testing interests and whether it appears to be a good faith attempt to present an agreement acceptable to EPA.

Under the current regulations, at § 790.22 (b)(1), where there is an ITC recommendation with intent to designate, solicitation for negotiation participants occurs at the same time the ITC report is published, rather than after EPA has had a chance to determine whether an ECA would even be an appropriate means for obtaining the test data in a given instance. In such circumstances, negotiation would begin before EPA is able to determine whether any party would be interested in submitting a testing proposal that might form an adequate basis to begin negotiations and before EPA has concluded that negotiating an ECA would likely be successful and more efficient than promulgating a test rule. EPA believes these circumstances create the unwarranted potential for wasting time and resources on negotiations over a clearly inadequate proposal. In EPA's judgment, not requiring that a minimally acceptable proposed testing agreement be submitted to, and evaluated by, EPA before commencing negotiations has contributed to substantial delay in ECA completion, which would be remedied by the proposed change.

Additional aspects of the current ECA regulations have also been found to contribute to delay. At present, the only time limits or deadlines in the ECA procedures are in the presumptive schedule in Appendix A to subpart E of part 790, and the provision in § 790.22(b)(6) that, in certain circumstances, EPA will terminate negotiations 10 weeks after the deadline for requests to participate in negotiations. EPA has found the schedule to be unrealistic in most circumstances in light of the number of steps it suggests, and notes that the schedule explicitly notes only one point when EPA could terminate negotiations, rather than whenever such negotiations become unproductive or unduly prolonged. Section 790.22(b)(6) currently permits EPA to terminate negotiations over chemicals that the ITC has recommended for testing with an intent to designate if the Agency concludes early in the process that negotiations will be fruitless ("EPA will terminate negotiations after 10 weeks and proceed with rulemaking unless negotiations are likely to result in a draft consent agreement within 4 additional weeks"). This opportunity occurs only ten weeks after the earliest time negotiations begin, before the comment period for the interested parties, and before the "comment resolution meeting." Further, there is no express provision at all for terminating unsuccessful ECA negotiations on chemical substances or mixtures that have not been recommended with intent to designate by the ITC (i.e., those substances that the ITC has simply recommended and those substances that EPA has selected on its own initiative).

EPA proposes to amend § 790.22 to expressly allow EPA to affirmatively terminate negotiations at any time it believes negotiations are unlikely to produce a final agreement, regardless of whether the chemical substance or mixture subject to the negotiation was selected for testing consideration based on an ITC recommendation-with-intent-to-designate, an ITC recommendation, or EPA's own initiative. Furthermore, the proposed amendments would provide that if negotiations have not concluded within six months (again, regardless of the circumstances by which the chemical substance or mixture was selected for testing consideration), ECA negotiations automatically terminate and EPA may pursue a test rule instead. For the cases in which the parties are very near agreement at the end of six months, EPA proposes that the rules be amended to permit EPA to provide one or more extensions of up to 60 days each where it seems likely to EPA that agreement will be reached in that additional time. EPA would notify all interested parties of any extension(s).

The current ECA regulations discuss a number of public meetings that do not seem to be necessary or helpful in many instances. Current § 790.22(a) and the schedule in Appendix A to subpart E of part 790 discuss a focus meeting that is to be held to discuss ITC recommendations-with-intent-to-designate. Current § 790.28 directs that the same schedule is to be followed for chemicals for which there has been no ITC designation or recommendation-with-intent-to-designate, making it unclear whether a public focus meeting must be used in situations other than when the ITC has made a recommendation-with-intent-to-designate. While such a meeting may be helpful as an initial public comment gathering tool when the ITC has made a recommendation-with-intent-to-designate, it is confusing to include this meeting in the procedures for negotiating an ECA because not all chemicals that the ITC recommends-with-intent-to-designate will ultimately be the subject of an ECA. Additionally, it would not be necessary to hold the focus meeting in other situations in which a chemical substance or mixture might be selected for testing consideration because there would not be an ITC recommendation-with-intent-to-designate to discuss (such as when EPA seeks testing data on its own initiative or based on an ITC recommendation without intent to designate).

The regulations at current § 790.22 call for a public meeting to discuss EPA's preliminary testing determinations—this is referred to in the regulations and in the schedule in Appendix A to subpart E of part 790 as the "course setting" meeting. These meetings are in addition to the ECA negotiation meeting or meetings (which are also public). EPA believes that it is unnecessary and unduly rigid to require a course setting meeting in all circumstances in which EPA intends to attempt to negotiate an ECA, regardless of need or public interest. Therefore, EPA proposes to retain this as a requirement only for ITC recommendations-with-intent-to-designate, and to move it from the ECA procedures (at § 790.22(a)(6) in the existing rule) to the ITC response procedures at § 790.20(b)(6) in this proposed rule.

EPA proposes to amend the rules so that the only meetings required by the ECA procedures, consolidated in proposed § 790.22, would be the negotiation meeting or meetings. Negotiation meetings under the proposed ECA procedures could include the draft ECA comment resolution meeting described in the current § 790.22(b)(8), so EPA believes it is unnecessary to include regulatory language in proposed § 790.22 expressly allowing for such a meeting. Other notices regarding EPA's views on testing needs, solicitation of interested parties to participate in negotiations, and invitations to submit draft testing agreement proposals can be efficiently accomplished through **Federal Register** documents, through the EPA website, and through other forms of public communication. In particular, the solicitation of interested parties to participate in negotiations through

Federal Register documents will be maintained.

The proposed amendments to § 790.22 reflect this streamlined, flexible approach to public meetings, and make several other minor changes to modernize and streamline the ECA negotiation and public communication process (e.g., rather than placing meeting minutes, other background documents, etc. into a "public file" in the OPPTS Reading Room, EPA is proposing to place these documents in an Internet-accessible public docket established by EPA at *http://www.regulations.gov*).

III. Statutory and Executive Order Reviews

A. Regulatory Review

Under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993), this proposed rule is not a "significant regulatory action" subject to review by the Office of Management and Budget (OMB) under Executive Order 12866, because it does not meet the criteria in section 3(f)(4) of the Executive Order. Accordingly, EPA did not submit this proposed rulemaking to OMB for review under Executive Order 12866.

B. Paperwork Reduction Act

This action does not impose any new information collection burden, because the development of an ECA does not involve information collection activities as defined by the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq*. However, the information collection requirements contained in an ECA are already approved by OMB pursuant to the PRA under OMB control number 2070–0033 (EPA ICR No. 1139). Under the PRA, an agency may not conduct or sponsor, and a person is not required to respond to, an information collection request unless it displays a currently valid control number assigned by OMB. The OMB control numbers for EPA's regulations in title 40 of the CFR are listed in 40 CFR part 9, and will be included in the individual ECAs.

C. Regulatory Flexibility Act

Pursuant to section 605(b) of the Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et seq.*, after considering the potential economic impacts of this proposed rule on small entities, the Agency hereby certifies that this proposed rule would not have a significant adverse economic impact on a substantial number of small entities.

Small entities include small businesses, small organizations, and small governmental jurisdictions. For purposes of assessing the impacts of today's proposed rule on small entities, small entity is defined as: (1) A small business as defined by the Small Business Administration's (SBA) regulations at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

This action will not have a significant economic impact on a substantial number of small entities. In determining whether a rule has a significant economic impact on a substantial number of small entities, the impact of concern is any significant adverse economic impact on small entities, since the primary purpose of regulatory flexibility analysis is to identify and address regulatory alternatives "which minimize any significant economic impact of the rule on small entities" (5 U.S.C. 603 and 604). Thus, an agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves regulatory burden, or otherwise has a positive economic effect on all of the small entities subject to the rule.

The proposed changes discussed in this document are expected to streamline and improve the ECA procedures in a way that will benefit all participants. EPA has therefore concluded that this proposed rule will not have any adverse impacts on affected small entities. However, EPA continues to be interested in the potential impacts of the ECA procedures on small entities and welcomes comments on issues related to such impacts.

D. Unfunded Mandates Reform Act

This action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4. Therefore, this action is not subject to the requirements of UMRA.

E. Federalism

Pursuant to Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999), EPA has determined that this proposed rule does not have "federalism implications," because it will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. Thus, Executive Order 13132 does not apply to this proposed rule.

F. Tribal Implications

Under Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000), EPA has determined that this proposed rule does not have tribal implications because it will not have any effect on tribal governments, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in the executive order. Thus, Executive Order 13175 does not apply to this proposed rule.

G. Children's Health Protection

Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 1985, April 23, 1997), does not apply to this action because this is not designated as an "economically significant" regulatory action as defined by Executive Order 12866 (see Unit III.A.), nor does this action establish an environmental standard that is intended to have a disproportionate effect on children. To the contrary, this action will revise procedures which will facilitate the development of data and information that EPA and others can use to assess the risks of chemicals, including potential risks to children.

H. Energy Effects

This action is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) because this action is not expected to affect energy supply, distribution, or use.

I. Technology Standards

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law No. 104–113, 12(d) (15 U.S.C. 272 note), directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides

not to use available and applicable voluntary consensus standards.

This proposed rulemaking does not involve technical standards. Therefore, EPA is not considering the use of any voluntary consensus standards.

J. Environmental Justice

This action does not involve special considerations of environmental justice related issues as delineated by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

List of Subjects in 40 CFR Part 790

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements.

Dated: February 2, 2010.

Stephen A. Owens,

Assistant Administrator, Office of Prevention, Pesticides and Toxic Substances.

Therefore, it is proposed that 40 CFR part 790 be amended as follows:

PART 790—[AMENDED]

1. The authority citation for part 790 continues to read as follows:

Authority: 15 U.S.C. 2603.

2. Section 790.1 is amended as follows:

a. By revising paragraph (c).

b. By removing paragraph (d).

§ 790.1 Scope, purpose, and authority.

* * * * *

(c) EPA intends to use enforceable consent agreements to accomplish testing where a consensus exists among EPA, affected manufacturers and/or processors, and interested members of the public concerning the need for and scope of testing.

3. Section 790.20 is revised to read as follows:

§ 790.20 Recommendation, recommendation with an intent to designate, and designation of testing candidates by the ITC.

(a) *Interagency Testing Committee (ITC) recommendations and recommendations with intent to designate.* The ITC has advised EPA that it will discharge its responsibilities under section 4(e) of the Toxic Substances Control Act (TSCA) in the following manner:

(1) When the ITC identifies a chemical substance or mixture that it believes should receive expedited consideration by EPA for testing, the ITC may add the substance or mixture to its list of chemicals recommended for testing and include a statement that the ITC intends to designate the substance or mixture for action by EPA in accordance with section 4(e)(1)(B) of TSCA.

(2) Chemical substances or mixtures selected for expedited review under paragraph (a)(1) of this section may, at a later time, be designated for EPA action within 12 months of such designation. The ITC's subsequent decision would be based on the ITC's review of TSCA sections 8(a) and 8(d) data and other relevant information.

(3) Where the ITC concludes that a substance or mixture warrants testing consideration but that expedited EPA review of testing needs is not justified, the ITC will add the substance or mixture to its list of testing recommendations without expressing an intent to designate the substance or mixture for EPA action in accordance with section 4(e)(1)(B) of TSCA.

(4) The ITC reserves its right to designate any chemical that it determines the Agency should, within 12 months of the date first designated, initiate a proceeding under section 4(a) of TSCA.

(b) *Preliminary EPA evaluation of ITC recommendations with intent to designate.* Following receipt of an ITC report containing a recommendation with an intent to designate, EPA will use the following procedure for completing a preliminary evaluation of testing needs on those chemical substances that the ITC has recommended with intent to designate.

(1) EPA will publish the ITC report in the **Federal Register** and announce that interested persons have 30 days to submit comments on the ITC's testing recommendations.

(2) EPA will publish a **Federal Register** document adding all ITC-recommended chemicals to the automatic reporting provisions of its rules under sections 8(a) and 8(d) of TSCA (40 CFR parts 712 and 716).

(3) EPA will hold a public "focus meeting" to discuss the ITC's testing recommendations and obtain comments and information from interested parties.

(4) EPA will evaluate submissions received under TSCA sections 8(a) and 8(d) reporting requirements, comments filed on the ITC's recommendations, and other information and data compiled by the Agency.

(5) EPA will make a preliminary staff determination of the need for testing and, where testing appears warranted, will tentatively select the studies to be performed.

(6) EPA will hold a public meeting to announce its preliminary testing determinations.

(c) *EPA response to ITC designations and recommendations.* (1) Where a substance or mixture is designated for EPA action under section 4(e)(1)(B) of TSCA, the Agency will take either one of the following actions within 12 months after receiving the ITC designation:

(i) Initiate rulemaking proceedings under section 4(a) of TSCA. Where the testing recommendations of the ITC raise unusually complex and novel issues that require additional Agency review and opportunity for public comment, the Agency may initiate rulemaking by publishing an Advance Notice of Proposed Rulemaking (ANPRM).

(ii) Publish a **Federal Register** document explaining the Agency's reasons for not initiating such rulemaking proceedings. EPA may conclude that rulemaking proceedings under section 4(a) of TSCA are unnecessary if it determines that the findings specified in section 4(a) of TSCA cannot be made or if the Agency entered into a consent agreement requiring the testing identified by the ITC.

(2) Where a substance or mixture has been recommended for testing by the ITC, whether with or without an intent to designate, EPA will use its best efforts to act on the ITC's recommendations as rapidly as possible consistent with its other priorities and responsibilities. EPA may respond to the ITC's recommendations with action such as:

(i) Initiating rulemaking proceedings under section 4(a) of TSCA,

(ii) Publishing a **Federal Register** document explaining the Agency's reasons for concluding that testing is unnecessary, or

(iii) Entering into a consent agreement in accordance with this subpart.

4. Section 790.22 is revised to read as follows:

§ 790.22 Procedures for developing consent agreements.

(a) *Preliminary EPA evaluation of proposed consent agreement.* Where EPA believes that testing of a chemical substance or mixture may be needed, and wishes to explore whether a consent agreement may satisfy the identified testing needs, EPA will invite manufacturers and/or processors of the affected chemical substance or mixture to submit a proposed consent agreement to EPA. EPA will evaluate the proposal(s) and may request additional clarifications of or revisions to the proposal(s).

(b) *Negotiation procedures for consent agreements.* If, after evaluating the proposed consent agreement(s), EPA

believes it is likely that proceeding with negotiation of a consent agreement would be an efficient means of developing the data, EPA will use the following procedures to conduct such negotiations:

(1) In the **Federal Register**, EPA will give notice of the availability of the proposal(s) that is the basis for negotiation, invite persons interested in participating in or monitoring negotiations to contact the Agency in writing, set a deadline for interested parties to contact the Agency in writing, and set a date for the negotiation meeting(s).

(2) The Agency will meet with interested parties at the negotiation meeting(s) for the purpose of attempting to negotiate a consent agreement. Only the submitter(s) of the proposal(s) that is the basis for negotiation and those persons who submit written requests to participate in or monitor negotiations by the deadline established under paragraph (b)(1) of this section will be deemed "interested parties" for purposes of this section.

(3) All negotiation meetings will be open to members of the public, but only interested parties will be permitted to participate in negotiations. The minutes of each meeting will be prepared by EPA. Meeting minutes, the proposed consent agreement(s), background documents and other materials distributed at negotiation meetings will be placed in an Internet-accessible public docket established by EPA.

(4) If EPA concludes at any time that negotiations are unlikely to produce a final agreement, EPA will terminate negotiations and may proceed with rulemaking. If EPA terminates negotiations, no further opportunity for negotiations will be provided. EPA will notify all interested parties of the termination.

(5) The period between the first negotiation meeting and final agreement, if any ("the negotiation period"), will be no longer than six months, unless extended prior to its expiration in accordance with paragraph (b)(7) of this section. This period will include all negotiation meetings, and the processes discussed in paragraphs (b)(6) and (b)(9) of this section. If the negotiation period passes without the production of a final agreement, negotiations and development of the subject ECA will terminate automatically.

(6) EPA will circulate a draft of the consent agreement to all interested parties if EPA concludes that such draft is likely to achieve final agreement. A period of 30 days will be provided for submitting comments or written objections under paragraph (b)(8)(i)(B) of this section.

(7) If, prior to the expiration of the negotiation period, final agreement has not been reached, EPA may at its discretion provide one or more extensions, each of which may be up to 60 days, if it seems likely to EPA that a final agreement will be reached during that time. EPA will notify all interested parties of any extension(s).

(8)(i) EPA will enter into consent agreements only where there is a consensus among the Agency, one or more manufacturers and/or processors who agree to conduct or sponsor the testing, and all other interested parties who identify themselves in accordance with paragraph (b)(2) of this section. EPA will not enter into a consent agreement in either of the following circumstances:

(A) EPA and affected manufacturers and/or processors cannot reach a consensus in the timeframe described in paragraph (b)(5) of this section.

(B) A draft consent agreement is considered inadequate by other interested parties who have submitted timely written objections to the draft consent agreement, which provide a specific explanation of the grounds on which the draft agreement is objectionable.

(ii) EPA may reject objections described in paragraph (b)(8)(i)(B) of this section only where the Agency concludes the objections:

(A) Are not made in good faith;

(B) Are untimely;

(C) Do not involve the adequacy of the proposed testing program or other features of the agreement that may affect EPA's ability to fulfill the goals and purposes of the Toxic Substances Control Act (TSCA); or

(D) Are not accompanied by a specific explanation of the grounds on which the draft agreement is considered objectionable.

(iii) The unwillingness of some manufacturers and/or processors to sign the draft consent agreement does not, in itself, establish a lack of consensus if EPA concludes that those manufacturers and/or processors who are prepared to sign the agreement are capable of accomplishing the testing to be required and that the draft agreement will achieve the purposes of TSCA in all other respects.

(9) Where a consensus exists, as described in paragraph (b)(8)(i) of this section, concerning the contents of a draft consent agreement, the draft consent agreement will be circulated to EPA management and the parties that are to conduct or sponsor testing under the agreement, for final approval and signature.

(10) Upon final approval and signature of a consent agreement, EPA will publish a **Federal Register** document announcing the availability of the consent agreement and codifying (in subpart C of part 799) the name of the substance(s) to be tested and the citation to the **Federal Register** document.

§§ 790.24, 790.26, and 790.28 [Removed]

5. Remove §§ 790.24, 790.26, and 790.28.

Appendix A to Subpart E of Part 790 [Removed]

6. Remove Appendix A to subpart E of part 790.

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 226

RIN 0648–AX06

Endangered and Threatened Species; Proposed Rule to Revise the Critical Habitat Designation for the Endangered Leatherback Sea Turtle; Extension of Public Comment Period

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Proposed rule; extension of public comment period.

SUMMARY: On January 5, 2010, NMFS proposed regulations to revise the critical habitat designation for the endangered leatherback sea turtle (*Dermochelys coriacea*) by designating additional areas within the Pacific Ocean. Specific areas proposed for designation include two adjacent marine areas totaling approximately 46,100 square miles (119,400 square km) stretching along the California coast from Point Arena to Point Vincente; and one 24,500 square mile (63,455 square km) marine area stretching from Cape Flattery, WA, to the Umpqua River (Winchester Bay), OR, east of a line approximating the 2,000 meter depth contour. The areas proposed for designation comprise approximately 70,600 square miles (182,854 square km) of marine habitat. NMFS is extending the comment period on the proposed regulations until April 23, 2010.